K052537

NOV 16 2005

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7 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h).

1. Identification of Submitter:

Submitter:	American Medical Sales, Inc.
Address:	4928 West Rosecrans Avenue
	Hawthorne, CA 90250-6616
Phone:	310-219-3200
Fax:	310-219-3201
Contact:	Carol M. Lifland
Title:	Vice President, Legal and Regulatory Affairs
Phone:	310-219-3200
Fax:	310-219-3201
Date Prepared:	September 13, 2005

2. Identification of Product:

Trade Name:	Catella Diagnostic Workstation, Version 4.0
Common Name:	Picture Archiving and Communications System
Classification Name:	Systems, Image Processing, Radiological
	21 CFR 892.2050 (Product Code LLZ)
Manufacturer:	American Medical Sales, Inc.
	4928 West Rosecrans Avenue
	Hawthorne, CA 90250-6616

3. Marketed Devices

The Catella Diagnostic Workstation, Version 4.0, is substantially equivalent to the devices listed below:

Model:	Seno Advantage
Manufacturer:	GE Medical Systems
510 (k) Number:	K033400
Model:	Sectra IDS5 Radiology Workstation
Manufacturer:	Sectra-Imtec Ab
510 (k) Number:	K033712, K040376

4. Device Description:

The Catella Diagnostic Workstation, Version 4.0 is a multi-modality PC-driven review workstation that operates on a standard Windows operating system. Each workstation may include a high performance computer, communications capability, medical grade, high-resolution monitors and video cards, trackball or mouse, microphone, keyboard, foot pedal and ergonomically designed display cart. The system is available for diagnostic and non-diagnostic workstations, including workstations designed as web-based, remote viewers or CD-viewer workstations. The software may be installed as a PC-based stand alone system, a software application, a web-based or SDK format, and is designed to be integrated with various DICOM compliant OEM systems.

The Catella Diagnostic Workstation, Version 4.0 includes the following software features:

- The Catella Diagnostic Workstation, Version 4.0 allows the user to select a study to view, archive, and perform administrative tasks.
- The Catella Diagnostic Workstation, Version 4.0 includes multi-modality viewing capabilities, allowing the user to view images from various modalities.
- Digitized mammographic images displayed on the Catella Diagnostic Workstation, Verison 4.0 must not be used for primary diagnostic interpretation.
- Lossy compressed mammographic images should not be used for primary diagnosis and contain a warning.
- DICOM query/retrieve and print, which allows retrieval of DICOM data from any DICOM-compliant device that is configured for query and retrieval.

The Catella Diagnostic Workstation, Version 4.0 also provides various software components described in the User Manual, including:

- Software for viewing images, playing audio, or viewing or dictating reports
- Zoom, pan, window/level
- Menu options
- Annotations, standard software tools
- Stack/Cine viewing mode
- DICOM query/receive

- DICOM-compliant methods of lossless and lossy image compression (JPEG2000 and JPEG)
- Outputs DICOM medical image data to printers that adhere to appropriate regulatory standards.
- Outputs medical imaging data in DICOM format to archives that use appropriate media that are designed to prevent data loss.
- Enables storage and reading of digitized images.

5. Indications for Use

The Catella Diagnostic Workstation, Version 4.0 is a medical image and information management system that allows easy viewing, selection, processing, printing, telecommunications, and media interchange of multi-modality medical images from a variety of diagnostic imaging systems. The Catella Diagnostic Workstation, Version 4.0 interfaces to various storage and printing devices using DICOM or similar interface standards. The system is available for diagnostic and non-diagnostic workstations, including workstations designed as web-based, remote viewers or CD-viewer workstations. The software may be installed as a PC-based stand alone system, a software application, a web-based or SDK format, and is designed to be integrated with various DICOM compliant OEM systems.

The Catella Diagnostic Workstation, Version 4.0 displays, stores, prints, and telecommunicates images from a number of medical modalities, including but not limited to MR, CT, DR, CR, X-ray, Angiography, Ultrasound, or digitizers. The Catella Diagnostic Workstation, Version 4.0 performs other user-defined post-processing functions, such as multi-planar reformatting of images. The PACS can display processed data from certain FDA-cleared third party image processing systems that create DICOM output. With proper links, the Catella Diagnostic Workstation, Version 4.0 also can invoke FDA-cleared third party image processing systems for advanced image processing, such as 3D display. It can also access RIS and HIS systems and can be used to review patient information.

The Catella Diagnostic Workstation, Version 4.0 is not intended for use for primary diagnostic interpretation of mammographic images.

6. Comparison with Predicate Devices

The Catella Diagnostic Workstation Version 4.0 is substantially equivalent to the following picture archiving and communications systems used by radiologists:

Seno Advantage Workstation
Manufacturer: GE Medical Systems
510 (k) Number: K033400

Sectra IDS5 Radiology Workstation
Manufacturer: Sectra-Imtec Ab
510 (k) Number: K040376

Each of these workstations allows easy selection, review, processing, archive, printing and media interchange of multi-modality images from a variety of diagnostic imaging systems.

7. Conclusions

The Catella Diagnostic Workstation, Version 4.0 provides specific software features to further integrate radiology department workflow. The potential hazards have been studied and controlled as part of the product development process, including risk analysis, test and design considerations, and planned verification and validation testing processes. The Catella Diagnostic Workstation, Version 4.0 provides images and data management capabilities comparable to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2005

Ms. Carol M. Lifland
Vice President, Legal and Regulatory Affairs
American Medical Sales, Inc.
4928 West Rosecrans Avenue
HAWTHORNE CA 90250

Re.: K052537
Trade/Device Name: Catella Diagnostic Workstation, Version 4.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system.
Regulatory Class: II
Product Code: LLZ
Dated: September 13, 2005
Received: September 15, 2005

Dear Ms. Lifland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6 Indication(s) for Use Statement

510(k) Number: ~~To be assigned by FDA~~ K052537

Device Name: Catella Diagnostic Workstation, Version 4.0

Indications for Use:

The Catella Diagnostic Workstation, Version 4.0, is a medical image and information management system that allows easy viewing, selection, processing, printing, telecommunications, and media interchange of multi-modality medical images from a variety of diagnostic imaging systems. The Catella PACS interfaces to various storage and printing devices using DICOM or similar interface standards. The system is available for diagnostic and non-diagnostic workstations, including workstations designed as web-based, remote viewers or CD-viewer workstations. The software may be installed as a PC-based stand alone system, a software application, a web-based or SDK format, and is designed to be integrated with various DICOM compliant OEM systems.

The Catella PACS displays, stores, prints, and telecommunicates images from a number of medical modalities, including but not limited to MR, CT, DR, CR, X-ray, Angiography, Ultrasound, or digitizers. The Catella Diagnostic Workstation, Version 4.0 performs other user-defined post-processing functions, such as multi-planar reformatting of images. The Catella PACS can display processed data from certain FDA-cleared third party image processing systems that create DICOM output. With proper links, the Catella Workstation also can invoke FDA-cleared third party image processing systems for advanced image processing, such as 3D display. It can also access RIS and HIS systems and can be used to review patient information.

The Catella Diagnostic Workstation, Version 4.0, is not intended for use for primary diagnostic interpretation of mammographic images.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052537